Richard A. Ramler
Jorden S. Ramler
Ramler Law Office, P.C.
202 West Madison
Belgrade, MT 59714
Telephone (406) 388-0150
Telefax (406) 388-6842
rramler@ramlerlaw.com
jramler@ramlerlaw.com

Attorneys for Plaintiff

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA
BUTTE DIVISION

TIMOTHY INMAN, Plaintiff, vs. DEPUY SYNTHES, INC.; DEPUY ORTHOPAEDICS, INC.; MEDICAL DEVICE BUSINESS SERVICES, INC.; DEPUY SYNTHES PRODUCTS, LLC; SYNTHES USA PRODUCTS, LLC; JOHNSON & JOHNSON; and DOES 1-10, Defendants.	Cause No. _____ **COMPLAINT AND DEMAND FOR JURY TRIAL**

Plaintiff, Timothy Inman, by and through his attorneys, and for his civil action against Defendants, states and alleges as follows:

PARTIES

1. Plaintiff, Timothy Inman (hereinafter "Plaintiff" or "Inman") is a citizen and resident of Gallatin County, Montana.

2. Defendant, DePuy Synthes, Inc. (hereinafter "DePuy Synthes") is, and at all times material hereto was, a corporation organized under the laws of the State of Delaware, with its principal place of business in Indiana.

3. Defendant, DePuy Orthopaedics, Inc. (hereinafter "DePuy Orthopaedics") is, and at all times material hereto was, a corporation organized under the laws of the State of Indiana, with its principal place of business in Indiana.

4. Defendant, Medical Device Business Services, Inc. f/k/a DePuy Orthopaedics, Inc. (hereinafter "Medical Device Business") is, and at all times material hereto was, a corporation organized under the laws of the State of Indiana, with its principal place of business in Indiana.

5. Defendant, DePuy Synthes Products, LLC (hereinafter "DePuy Products") is, and at all times material hereto was, a limited liability company organized under the laws of the State of Indiana, with its principal place of business in Massachusetts.

6. Defendant, Synthes USA Products, LLC (hereinafter "Synthes Products") is, and at all times material hereto was, a limited liability

company organized under the laws of the State of Delaware, with its principal place of business in Massachusetts.

7. Defendant, Johnson & Johnson (hereinafter "Johnson & Johnson") is, and at all times material hereto was, a corporation organized under the laws of the State of New Jersey, with its principal place of business in New Jersey.

8. Defendants Does 1-10 were and now are business entities duly organized and existing under the laws of the states of the United States, or a foreign country, whose names, citizenship, and principal places of business Plaintiff does not know and cannot now ascertain. These presently unknown Doe entities are alleged to have been engaged in the design, manufacture, assembly, distribution, and sale of joint replacement products, including the DePuy Sigma TC3 Total Knee Arthroplasty Implant System (hereinafter "Sigma TC3") involved in this civil action. Plaintiff brings this civil action against said Doe Defendants by such fictitious names and will ask leave to amend this Complaint to show their true name(s) and the name of such states and/or countries when ascertained.

9. Defendants DePuy Synthes, DePuy Orthopaedics, Medical Device Business, DePuy Products, Synthes Products, Johnson & Johnson, and Does 1-10, shall hereafter, jointly and severally, be referred to as "Defendants" or "DePuy."

10. At all times relevant herein, Defendants were the agents and alter egos of each other. As agents and alter egos, each Defendant was acting within the course and scope of its agency and was subject to and under the supervision and authority of its Co-Defendants in regard to the allegations herein.

11. At all times relevant herein, Defendants, jointly and severally, were "sellers" as defined under Mont. Code Ann. § 27-1-719, and apparent manufacturers of the Sigma TC3.

JURISDICTION AND VENUE

12. This Court has jurisdiction over this matter pursuant to 28 U.S.C. § 1332 in that Plaintiff is a citizen of the State of Montana, Defendants are corporate citizens of states other than Montana, and the amount in controversy exceeds Seventy-Five Thousand ($75,000.00) Dollars, exclusive of interest and costs.

13. This Court has personal jurisdiction over Defendants because Defendants maintain significant contacts with this judicial district by virtue of conducting business within the district through their distribution, sales, marketing and advertising in Montana, including the distribution and sale of the defective Sigma TC3 that caused injury and damage to Plaintiff in Montana.

14. Venue is proper within the Butte Division because the incident that gives rise to this civil action occurred within Gallatin County, Montana.

COMMON ALLEGATIONS

15. Plaintiff resides in Gallatin County, Montana, and is a resident of the State of Montana. Plaintiff was a resident of Gallatin County, Montana, at the time of the incident that gives rise to this civil action.

16. Defendants are engaged in the business of designing, manufacturing, assembling, distributing and selling joint replacement products, including the Sigma TC3.

17. Defendants designed, manufactured, marketed, distributed, and sold the Sigma TC3, knowing and expecting that the Sigma TC3 would be used by consumers, such as Inman.

18. Defendants are the manufacturer and/or apparent manufacturer of the Sigma TC3.

19. On December 13, 2011, Inman underwent left revision total knee arthroplasty with implant of a Sigma TC3 by Dr. Daniel Gannon in Bozeman, Montana.

20. The Sigma TC3 was recommended because Inman had an active lifestyle. Inman owned and operated Bridger Garage Door Company and enjoyed hunting, fishing, horseback riding, and dog training.

21. Inman was told that the Sigma TC3 would last 20 – 30 years and then only the poly insert would need to be replaced.

22. On or about February 24, 2021, Inman was walking on the driveway to his home in Gallatin County, Montana, and felt a clunk with the onset of left knee pain. The clunk and onset of left knee pain was not the result of an accident, trauma, or some other unusual event.

23. On March 3, 2021, Inman underwent x-rays at Bridger Orthopedic in Bozeman, Montana, which revealed a fractured modular femoral stem bolt in the Sigma TC3 implant.

24. As a result of the fractured modular femoral stem bolt, Inman underwent left revision total knee arthroplasty by Dr. Christopher Earl Pelt at Utah Hospital, Salt Lake City, Utah, on March 15, 2021.

25. Upon information and belief, Defendants were able to avoid a lengthy and expensive FDA approval process for the Sigma TC3 implant system by representing that it was similar to other knee implant systems that had been used for some time.

26. There have been other similar incidents and reports of failure of the Sigma TC3 implant system with fracture of the modular femoral stem bolt.

27. Plaintiff's damages include past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earning capacity, future revision surgery and left above knee amputation, disability, disfigurement, loss of established course of life, and other general and special damages to be determined by the jury at trial of this action.

COUNT ONE

Strict Liability – Design and Manufacturing Defects

28. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

29. The Sigma TC3 implant system was in a defective condition in violation of Section 27-1-719, M.C.A. when the Sigma TC3 was sold to Plaintiff and when the modular femoral stem bolt in the Sigma TC3 fractured on or about February 24, 2021.

30. Defendants intended that the Sigma TC3 implant system and the components at issue, which were designed, manufactured, produced, assembled, made, marketed, distributed and/or sold by them, to be used as a knee replacement system.

31. Defendants are sellers as defined in Section 27-1-719, M.C.A., and are engaged in the business of selling joint replacement products, including the Sigma TC3.

32. At all relevant times hereto, Defendants were engaged in the business of designing, manufacturing, distributing, marketing, and selling joint replacement products, including the Sigma TC3, and in this regard, did design, manufacture, distribute, market, and sell the Sigma TC3 which is the subject of this action, knowing and expecting that the Sigma TC3 would be used by consumers including Plaintiff and members of the general public.

33. The Sigma TC3 was defective, unreasonably dangerous and unsafe for its intended purpose at the time it left the possession of Defendants.

34. The Sigma TC3 which is the subject of this action was sold to and implanted in Plaintiff without substantial change in the condition in which it was manufactured and/or sold

35. Inman's knee implant failed due to a fatigue fracture of the modular femoral stem bolt in the femoral component of the Sigma TC3.

36. Inman's knee implant failed because it was defectively designed and manufactured.

37. The Sigma TC3 is defectively designed because Defendants selected a material for the femoral stem bolt that was not adequate to meet the fatigue, fretting, and corrosion clinical environment for its intended use.

38. The Sigma TC3 is defectively designed because the implant system was designed in such a manner that allows the femoral stem bolt to fracture.

39. The Sigma TC3 is defectively designed because the femoral stem bolt has the propensity to fracture following implantation.

40. The Sigma TC3 was marketed in such a way as to mislead consumers regarding its use, safety, and efficacy.

41. The Sigma TC3, including the modular femoral stem bolt, was inadequately tested.

42. The Sigma TC3, and in particular, the modular femoral stem bolt was defectively manufactured which caused the bolt to fracture.

43. Defendants are strictly liable to Plaintiff for Plaintiff's general and special damages resulting from the sale of the defective Sigma TC3.

44. The defective condition of the Sigma TC3 caused Plaintiff's injuries and damages.

45. The Sigma TC3 failed to perform as ordinary patients and medical professionals would expect.

46. Plaintiff used the Sigma TC3 for its intended purpose.

47. As a result of the defective condition of the Sigma TC3, Plaintiff has and will suffer past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earning capacity, left above knee amputation,

disability, disfigurement, loss of established course of life, and other general and special damages in an amount to be determined by the jury at trial of this action.

COUNT TWO

Strict Liability-Failure to Warn

48. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

49. Defendants knew, or in the exercise of ordinary care should have known, of the Sigma TC3's propensity to fail, but failed to notify or warn Plaintiff or the surgeon of this propensity, either before or after the purchase and implant of the Sigma TC3.

50. The Plaintiff, the surgeon, and the general public did not recognized the risk of failure associated with the Sigma TC3.

51. Defendants owed a duty to users including Plaintiff and the surgeon to adequately warn of the propensity of the Sigma TC3 to fail at the time of and after the sale and implant of the Sigma TC3.

52. Failure to warn Plaintiff and the surgeon of the risks associated with the Sigma TC3 was a breach of Defendants' duties to Plaintiff and the

surgeon to provide adequate warnings, both before and after the sale of the SigmaTC3.

53. Defendants' failure to adequately warn caused Plaintiff's injuries and damages.

54. As a result of Defendants failure to warn, Plaintiff has and will suffer past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earning capacity, future revision surgery and left above knee amputation, disability, disfigurement, loss of established course of life, and other general and special damages in an amount to be determined by the jury at trial of this action.

COUNT THREE

Negligence

55. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

56. At all relevant times herein, Defendants owed Plaintiff a duty to exercise reasonable care in the design, formulation, testing, manufacture, marketing, sale, and distribution of the Sigma TC3 knee implant system, and primarily the femoral component of the Sigma TC3, including a duty to ensure that the modular femoral stem bolt did not fail due to fatigue fracture.

57. Defendants breached the duties they owned to Inman, failed to exercise reasonable care, and were negligent including, but not limited to, the following:

a. Designing, manufacturing, marketing, and selling the Sigma TC3 when the modular femoral stem bolt has high propensity to fracture.

b. Failing to adequately warn consumers in general, and Inman and his surgeon in particular, of the risk that the modular femoral stem bolt could fracture.

c. Making false representations concerning the safety, durability, anticipated life expectancy, and efficacy of the Sigma TC3.

d. Selling and placing the Sigma TC3 into the stream of commerce when it had not been adequately tested.

e. Failing to property test the Sigma TC3 before making representations concerning the safety, durability, anticipated life expectancy, and efficacy of the Sigma TC3.

f. Failing to properly test the Sigma TC3 before marketing it as safe for implantation in the human body.

g. Failing to properly test or warn after receiving notice of other Sigma TC3 failures because of modular femoral stem bolt fracture.

58. The character of the incident that made the basis of this action is such that it would not have ordinarily occurred without negligence.

59. The components of the Sigma TC3 knee implant were under the management and control of Defendants. Defendants were in control of the components of the Sigma TC3 at the time the negligence occurred.

60. The jury should infer the negligence of Defendants under the doctrine of res ipsa loquitur.

61. As a result of Defendants' negligence, and failure to use reasonable care, Plaintiff has and will suffer past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earnings capacity, future revision surgery and left above knee amputation, disability, disfigurement, loss of established course of life, and other general and special damages in an amount to be determined by the jury at trial of this action.

COUNT FOUR

Consumer Protection Act

62. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

63. At all times relevant to this action, the Montana Consumer Protection Act, Mont. Code Ann. §§ 30-14-101 *et. seq.* was in effect and expressly precluded

as unlawful the "unfair or deceptive acts or practices in the conduct of any trade or commerce." Mont. Code Ann. § 30-14-103.

64. An unfair act or practice includes one that offends public policy and which is either immoral, unethical, oppressive, unscrupulous, or substantially injurious to consumers.

65. Plaintiff purchased the Sigma TC3, including its component parts, for personal use.

66. Defendants marketed, distributed, and sold the Sigma TC3 implant system in the State of Montana. These acts constitute acts of trade or commerce in the State of Montana.

67. Defendants' unfair or deceptive acts or practices include, but are not limited to, fraudulent concealment and knowing and false representations of material facts to consumers, and the failure to timely alert consumers of the problems and risks which were or should have been discovered regarding the Sigma TC3 implant system. Defendants' deceptive and unfair acts were made for the purpose of procuring and promoting the sale of the Sigma TC3 implant system and other similar components.

68. Defendants allowed their defective and unreasonably dangerous Sigma TC3 implant components to be implanted despite indications they

could fail, necessitating additional surgeries, including above knee amputation.

69. Defendants misled and misrepresented the efficacy and reliability of the Sigma TC3 implant system, and its components.

70. Defendants failed to take steps to warn patients, surgeons, or other healthcare professionals about the risk of failure of the Sigma TC3 and its components.

71. Defendants' representations, omissions, and practices were likely to mislead patients, surgeons, and other healthcare professionals, and in fact, misled Inman, his surgeon, and other healthcare providers, including that Defendants' Sigma TC3 implant system, and its components, were safe and reliable for implantation.

72. Defendants' conduct constituted an unfair and deceptive practice in the conduct of business.

73. As a result of Defendants' unfair and deceptive practices, Plaintiff has and will suffer past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earnings capacity, future revision surgery and left above knee amputation, disability, disfigurement, loss of established course of life, and other general and special damages in an amount to be determined by the jury at trial of this action.

74. Plaintiff is entitled to compensation under the Consumer Protection Act, including treble damages, attorney fees, and costs. Mont. Code Ann. § 30-14-133.

COUNT FIVE

Breach of Warranty

75. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

76. Prior to and at the time of implant of the Sigma TC3, and Plaintiff's use of the Sigma TC3 implant for its intended purpose, Defendants' expressly and impliedly warranted to Plaintiff that the products were of merchantable quality and reasonably fit, reliable, and safe for their ordinary use and intended purpose.

77. At the time of contracting for sale and the retail sale of the subject Sigma TC3 implant system and components, Defendants knew or should have known the particular purpose for which the goods were required and that Plaintiff and other consumers were relying upon Defendants' skill and judgment to provide suitable goods.

78. In a reasonable and foreseeable manner, Plaintiff relied on Defendants' express and implied representations and warranties in consenting to knee replacement surgery with Defendants' devices.

79. Defendants breached their express and implied representations and warranties in regarding the safety and merchantability and fitness for a particular purpose of their devices.

80. The subject Sigma TC3 implant system and components were not safe, not reliable, not fit for their intended use, and not of merchantable quality as warranted by Defendants.

81. Defendants knew or had reason to know that the subject devices and components were not safe, not reliable, not fit for their intended use, and not of merchantable quality as warranted by Defendants.

82. As a proximate result of Defendants' breach of warranties, Plaintiff has suffered injuries, losses, and damages recoverable herein.

83. As a result of Defendants' breach of express and implied warranties, Plaintiff has and will suffer past and future medical expense, mental and physical pain and suffering, loss of earnings, impaired earnings capacity, future revision surgery and left above knee amputation, disability, disfigurement, loss of established course of life, and other general and special damages in an amount to be determined by the jury at trial of this action.

COUNT SIX

Punitive Damages

84. Plaintiff hereby incorporates by reference all of the allegations previously made herein.

85. Defendants' conduct, as described here, constitutes actual fraud and actual malice as defined in Mont. Code Ann. § 27-1-221.

86. Defendants knew or should have known of the defects alleged in this Complaint and that catastrophic injuries could occur and have occurred due to selling a Sigma TC3 that was defectively designed and manufactured and due to their failure to adequately warn. Nonetheless, the defects were not corrected by Defendants, nor did Defendants warn the public including Plaintiff about these defects and the risks they posed.

87. Instead, Defendants deliberately and intentionally concealed such information from Plaintiffs and the public. Defendants acted with malice in that Defendants had knowledge of facts and intentionally disregarded facts that created a high probability of damage to Plaintiff and deliberately proceeded to act in conscious and intentional disregard of the high probability of injury to Plaintiff, and deliberately proceeded to act with indifference to the high probability of injury to Plaintiff.

88. Defendant further knowing made false representations concerning the quality, useful life, function and design of the Sigma TC3,

and concealed material facts concerning the fact that the Sigma TC3 could fail causing injury to Plaintiff.

89. As a result, Plaintiff is entitled to recover punitive damages from Defendants in an amount to be determined by the jury at trial.

WHEREFORE, Plaintiff prays for judgment, jointly and severally, against the Defendants as follows:

1. For general and special damages in an amount to be determined at trial.

2. For treble actual damages, costs, and attorneys' fees pursuant to Mont. Code Ann. § 30-14-133.

3. For punitive damages in an amount to be determined at trail.

4. For costs and expenses.

5. For such and further relief as the Court deems just and proper.

DATED this 14th day of December, 2022.

Ramler Law Office, P.C.

By: /s/Richard A. Ramler
Richard A. Ramler
Attorney for Plaintiff

DEMAND FOR JURY TRIAL

Plaintiff, by and thought his attorney, hereby demands a trial by jury in the above-entitled cause.

Ramler Law Office, P.C.

By:/s/Richard A. Ramler
Richard A. Ramler
Attorney for Plaintiff